

## WHO to oversee genome editing

The World Health Organization (WHO) in February unveiled an expert advisory panel to oversee and provide guidance on human genome editing. The panel was convened in response to Chinese researcher Jiankui He's announcement that he had edited the genomes of twin girls and the global outcry that followed (*Nature* 563, 7733, 2018). By setting up a committee with experts from around the globe, WHO will seek to advise and guide its members on the scientific, ethical, social and legal challenges associated with human genome editing.

The 18-strong panel, made up of multinational and multidisciplinary experts, will be cochaired by Edwin Cameron, a judge on South Africa's Constitutional Court, and Margaret Hamburg, who is chair of the American Association for the Advancement of Science (AAAS). The group will work with other international bodies and national academies to promote transparency and ensure that research institutions carry out appropriate risk/benefit assessments before authorizing any human genome editing.

Similar efforts have already sprung up elsewhere. In Europe, researchers launched the Association for Responsible Research and Innovation in Genome Editing (ARRIGE), which aims to include a broad array of stakeholders in the discussion. At the same time, a pair of scholars proposed a gene editing observatory modeled on international networks that monitor climate change and human rights (*Nat. Biotechnol.* 36, 6, 2018).

Another view is that the gene editing community must police itself. According to an editorial in this journal: "Researchers have a responsibility to report rogue practitioners to regulators" (*Nat. Biotechnol.* 37, 1, 2019). National governments, too, are stepping up to regulate human genome editing. China's National Health Commission in February announced draft regulations that put human genome editing under the authority of the State Council, the country's national cabinet.

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# Berkeley strikes back in CRISPR patent tussle

University of California and Broad dominant position on CRISPR intellectual property may augur licensing uncertainty.

The US Patent and Trademark Office (USPTO) has alerted the University of California that a CRISPR–Cas9 patent application filed in 2013 is now about to be issued. The USPTO's decision means that for now at least, both the University of California and the Broad Institute of Harvard and MIT hold foundational patents for CRISPR–Cas9 technology. Companies hoping to commercialize CRISPR–Cas9 face uncertainty over whether to obtain a license from University of California, Broad or both institutions.

The dispute between University of California and Broad over CRISPR–Cas9 patent rights began in 2014 when the USPTO granted Broad a set of patents for editing eukaryotic genomes, which the University of California challenged. Most recently, in September 2018, a US appeals court affirmed Broad's ownership of its foundational patents describing the use of CRISPR–Cas9 in eukaryotic cells (*Nat. Biotechnol.* 36, 1026, 2018), but also ruled that University of California's application, which describes CRISPR–Cas9 in any cell type and in cell-free systems, did not interfere with Broad's eukaryotic patents, meaning both methods could be patentable.

Until that court decision, the fate of the University of California's patent application (13/842,859; known as '859) was in limbo, but on February 8, the USPTO issued a 'notice of allowance' meaning that it is expected to issue in April or May of this year. Although Broad's patents clearly describe the use of CRISPR–Cas9 in eukaryotic cells, companies may now be left grappling whether a license to the University of California patent is also needed for work in eukaryotic cells, given that this patent covers CRISPR–Cas9 use in any cellular or non-cellular environment.

"Which CRISPR–Cas9 patents to license is very difficult question to answer at the moment," says Katherine Rubino, a patent attorney at Caldwell Intellectual Property Law. "It will depend on what application of the technology a potential licensee is going to use; for example, in what cell type. I think at some point in the future, the patent will be challenged and the result of this litigation will give us a more definitive answer," she says.

Yet Editas Medicine, which was founded by Broad scientists and has exclusive license to patents issued to the Broad Institute, is confident in its current



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